UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,344	01/25/2002	Won Kyu Kim	1599-0212P	9311

2292 7590 02/11/2003

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/11/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/055,344	Kim et al.
Examiner	**Art Unit**
Patricia Patten	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-10 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on Jan 25, 2002 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-10 are pending in the application.

Election/Restriction

Applicant's election of species in Paper No.3 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-10 were presented for examination on the merits.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Korea on 5/15/2001. The copy of the priority document has been received.

Drawings

The drawings are objected to because Figure 3 fails to display units with regard to the numbers on the Y axis. Figure 3 shows Anti-fatigue activity. It is not known what 2.0 anti-fatigue activity is. Are these numbers representative of a calculation which was performed on the data taken from Table 2? Further, Fig. 4 displays two asterisks, as well as a symbol above the 'Wild ginseng' bar. Figure 5 also displays a symbol above the 'Wild ginseng' bar and displays one asterisk above the bar. The Examiner cannot determine what these symbols mean, as they are not described in the description of the drawings. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

The term 'recithin' is found throughout the Specification. Upon searching the term 'recithin', it appears that this is an idiomatic term form 'lecithin' considering that 'recithin' was only found in translated Japanese patent abstracts. It appears that Applicants mean 'lecithin'. If

this is the case, it is asked that Applicants amend the occurances of 'recithin' in the Specification to recite 'lecithin'.

Appropriate correction is required.

Claim Objections

Claims 6, 9 and 10 are objected to for the following informalities:

Claim 6 recites '....wherein the grains or vegetables are selected from the group consisting of glutinous rice, unpolished rice, Job's-tear, barley, soy bean, pumpkin and mung bean and mixtures thereof'. However, because the claim states 'grains *or* vegetables' the species in the Markush group do not satisfy each genus. Because the claim states 'or', the species in the Markush group should correspond to each genus (grains and vegetables) respectively. In the Instant case, the members of the Markush group are drawn to grains and vegetables. Although it is apparent that Applicant means that the grains are selected from glutinous rice, unpolished rice, Job's-tear and barley, and that the vegetables are selected from soy bean, mung bean and pumpkin, and that these grains and vegetables may be mixed, the syntax of the claims is incorrect. It is suggested that Applicants write two new independent claims which recite two separate Markush groups for each of grains and vegetables.

It is noted that Applicants elected the species of the combination of all of the species found in claim 6. Thus, the claims were examined on the merits as if the claims were separated and respectively recited:

'Wherein the grains are glutinous rice, unpolished rice, Job's-tear and barley', and

'Wherein the vegetables are soy bean, mung bean and pumpkin'.

Claim 10, line 3, recites 'recithin'. The term 'recithin' was only found in very few abstracts of Japanese patents. Thus, it appears that Applicants mean 'lecithin' and that the term 'recithin' is an idiomatic term. If this is the case, Applicants are asked to amend the claim to recite 'lecithin' in order to overcome this objection. Further, claim 10 was examined on the merits as if the phrase read 'lecithin'.

Claim 9 recites 'injection'. This appears to be a syntax error because the agent would not be formulated into an 'injection' per se. The agent would typically be formulated into a solution for injection. Thus, the phrase is grammatically awkward. It is suggested that Applicant either amend the term to read 'solution for injection' or delete the term to overcome this objection.

Further, claim 9 recites 'formulated into....solution,....or concentrated solution'. Since 'solution and concentrated solution' are singular, an 'a' should be placed before the subject; i.e., ' a solution, 'a concentrated solution'.

Correction is necessary.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'the mixed powder'. This phrase lacks antecedent basis in the claim because 'mixed powder' was not previously mentioned in the claim.

Claim 7 recites 'an ordinary amount of vitamins' and 'an ordinary amount of amino acids'. While Applicants may understand what this means, these terms are considered indefinite

because the Examiner does not know what an 'ordinary amount' of vitamins or amino acids are. Do Applicants mean the recommended daily allowance of vitamins as according to the FDA, or some other amount which was recited in the Instant disclosure? The term 'ordinary' is a vague term which does not allow the Examiner to determine the meets and bounds of the intended amounts or even ranges of amounts. A clear definition of 'ordinary amount' was not found in the Instant specification as filed. It is suggested that Applicants amend the claim to recite a definite amount or range without adding new matter to the disclosure in order to overcome this rejection.

Claim 8 recites 'food engineeringly'. The Examiner cannot determine what this phrase means. It appears that Applicants may wish to recite 'food supplements' but the Examiner is not sure. 'Food engineeringly' is awkward in that the adverb, 'engineeringly' has been placed after the noun 'food', while adverbs are typically descriptive terms for verbs. Even if the term 'engineeringly' were placed in front of the noun; i.e., 'engineeringly food', the phrase is still confusing. In the Instant case, the Examiner cannot determine what Applicants mean by this phrase, and thus, it is deemed that the phrase is indefinite because the ordinary artisan would also have trouble ascertaining what Applicants mean by this phrase. Applicants are asked to amend the claim to particularly recite a clearly understood constituent in the claim.

Claim 9 recites 'The agent...which is formulated into....essence'. The term 'essence' here is confusing in that it is not clearly understood what Applicants mean by the term 'essence'. This

may be an idiomatic term, but the Examiner is not sure. This term (in English, while referring to plants and herbs) is typically used to refer to the flavor or aroma of a plant. However, it appears, judging from translations of Japanese patent abstracts, that this term may mean the active ingredient of the plant (or the active ingredient that the particular patent is referring to). Thus, the Examiner does not know what form an 'essence' is especially lacking any clear definition within the Specification. It is suggested that Applicants replace the term 'essence' with a more clearly defined form or to delete the term in order to overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sha et al. (US 2001/0055624 A1) or Sha et al. (US 6,280,776 B1) in view of Castleman (1991) in view of Lust (1974) and further in view of Ericsson (US 5,773,241).

It is noted that the elected species from claim 2 is free of the art. Thus, the Examiner has chosen another species of claim 2, 'Eucommia cortex' for examination on the merits.

Sha et al. (US 2001/0055624 A1) or Sha et al. (US 6,280,776 B1) (further referred to as '624 and '776 respectively) disclosed a product comprising hot water extracts of Panax pseudo-ginseng and Eucommia leaves, fruit and bark which they termed 'Denhichi-Tochu-Sei" ('624 p.2 [0017]-[0018], p.3, [0054], [0059] and [0062]/ '776 col.2, line 66- col.3 line 6, col.3, line 64-col.4, line 24). '624 and '776 both suggested that the extracts were added to honey and Panax ginseng, wherein honey could have served as an emulsifier to produce tablets (See for example, '624 pp.3 [0054] and '776 col.3, lines 4-6). '624 and '776 both recited wherein the dried herbs were minced prior to extraction (i.e., '776, col.3, line 65-66 and '624 p.3 [0054]. Example 1 of both '624 and '776, teach a preferred embodiment wherein the Denhichi-Tochu-Sei granule contained 30% by weight of Eucommia bark and 40% by weight of Panax pseudo-ginseng ('624 p.4 and '776, col.5). Further, Table 1 in each respective reference taught that free amino acids were present in varying amounts ('642 p.4 and '776 col.5). '624 and '776 both proposed the incorporation of Denhichi-Tochu-Sei into suitable medicinal/nutritional forms such as food supplements, and suggested the addition of Denhichi-Tochu-Sei into foodstuff such as cakes, candy, bread, wine, liquor, curry and health foods ('624 p.3 [0062] and [0067], '776 col.4, lines 40-42 and 61-63).

It is noted that cortex *is* bark, and therefore Eucommia bark is equivalent to the Eucommia cortex as recited in claim 2. Although the combination of bark, leaves and fruit were present in the product post-extraction, the product contained 'Eucommia cortex'. It is further noted that claim 1 states 'containing' which is open language which does not preclude the composition from containing ingredients which are not explicitly recited in the claims.

It is deemed that honey, which was a suggested emulsifier for the tablet form of the composition, was within the metes and bounds of a 'pharmaceutically acceptable carrier' in that honey would have acted as a suitable oral vehicle for the composition as disclosed by '624 and '776 (Claim 8).

Neither '624 nor '776 specifically disclosed wherein the Panax pseudo-ginseng was wild, nor wherein the herbs were powdered prior to extraction with water.

Castleman (1991) taught that "...all three [American, Siberian and Korean Ginseng] were grouped together as 'ginseng' and used interchangeably in the west" (p.193). Thus, it was known in the art that the term 'Ginseng' encompassed all species of Ginseng such as American and Korean ginseng and that these species were used interchangeably due to their similar intrinsic characteristics.

Lust (1974) speaking of Panax quinquefolius, stated that "Like its cultivated Oriental counterpart, however, it is not considered as efficacious as the wild plant" (p.207).

Powdering herbs prior to extraction was routine in the art at the time the Invention was made. Ericsson (US 5,773,241) taught that:

> "Grinding or mincing a plant or herb means that the harvested botanical is mechanically broken down into smaller units, ranging from larger course fragments to a fine powder. The most common machine to be used is the hammer mill, knife mill and teeth mill. Preferably, the comminution step is followed by a fine grinding step, for example, in a commercial blender to reduce the plant part to the smallest particles possible without damaging the bioactive ingredients. In this manner, **the surface area of each particle is increased and, therefore, the opportunity for more complete extraction of the vital chemical substances is enhanced**" (emphasis added) (col.2, lines 54-65).

One of ordinary skill in the art would have been motivated to have substituted the Panax pseudo-ginseng for wild Panax-pseudo ginseng in the composition disclosed by Sha et al. ('624 or '776) in order to provide a composition which was considered more medicinally potent. It was clear from Castleman et al. that varieties of Ginseng were obvious medicinal substitutes for one another. It was further clear that 'wild' Ginseng was preferred over cultivated Ginseng due to the wild Ginseng's improved efficacy. Thus, the ordinary artisan would have had a reasonable expectation that wild Ginseng would have provided similar medicinal properties with improved potency, especially lacking convincing evidence to the contrary.

One of ordinary skill in the art would have been motivated to powder the plants prior to extraction because in the powdered form of the herbs would have offered a suitable yield of medicinal components. It was clear from Ericsson that powdering herbs for extraction was an acceptable means of yielding active ingredients of plant materials. Thus, the ordinary artisan would have had a reasonable expectation that powdering the ginseng/Eucommia mix prior to extraction would have created a larger surface area of the plant material in order for the solvent (in this case, water) to penetrate the plant material thereby affecting a larger yield of water-soluble phytochemicals.

Claims 3, 4, 6, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sha et al. (US 2001/0055624 A1) or Sha et al. (US 6,280,776 B1) in view of Castleman (1991) in view of Lust (1974) in view of Ericsson (US 5,773,241) as applied to claims 1, 2, 5, 8 and 9 above, and further in view of Hastings (US 5,567,424).

It is noted that claim 3 was examined on the merits with regard to the elected species (vitamins, and analogues thereof, amino acids, grains and vegetables). It is further noted that claim 3 states 'one or more...vitamins....amino acids...grains and vegetables.' Thus, the claim may be drawn to *one* of each species even though the species are recited in the plural.

With regard to claim 4, the elected species is free of the art. Therefore, the Examiner has chosen the species of Vitamin A, Vitamin B and Vitamin E for examination on the merits. With regard to Claim 6, the elected species of vegetables; pumpkin and soy bean is free of the prior art. The Examiner searched the species pumpkin and soybean separately as well, and they are free of the art. The elected species of grains (glutinous rice, unpolished rice, Job's-tear and barley) is also free of the art, however, the Examiner chose another species, 'barley', for examination on the merits. Because these grains/vegetable species are combined in one claim (please see objection *supra*), the entire claim was rejected over the prior art even though the species of vegetables was free of the art. The rejection follows.

The teachings of Sha et al. (US 2001/0055624 A1), Sha et al. (US 6,280,776 B1), Castleman (1991) , Lust (1974) and Ericsson (US 5,773,241) were discussed *supra.*

None of the references specifically disclosed the addition of a supplement which included vitamins C, E and A, a grain such as barley, a vegetable or lecithin.

Hastings (US 5,567,424) disclosed a supplement for maintaining good health which included Vitamin C, Vitamin E, Vitamin A ('Antioxidants' col.4), pearl barley (a grain), Oriental Ginseng, Siberian Ginseng, and fenugreek (a vegetable) (Table 1, col.6). Hastings taught that the supplement could further include lecithin (an emulsifier) (col.5, lines 49-50).

One of ordinary skill in the art would have been motivated to have combined the composition 'Denhichi-Tochu-Sei' as disclosed by Sha et al. with the composition suggested by Hastings in order to provide a nutritional supplement with additional nutritious ingredients/medicinal qualities. Both '642 and '776 taught that the composition could have been 'added to cakes, candy , bread, wine, liquor, curry and any health-care food' ('624 p.3 [0062] and [0067], '776 col.4, lines 40-42 and 61-63). It is deemed that the composition disclosed by Hastings was a 'health-care food' in that Hastings suggested the supplement for 'maintaining good health'(Abstract and col.2, lines 48-56). Because '642 and '776 suggested the incorporation of 'Denhichi-Tochu-Sei' into a health-care food, the ordinary artisan would have had a reasonable expectation that addition of 'Denhichi-Tochu-Sei' into the health supplement disclosed by Hastings would have afforded additional nutrients to the supplement. Further, Hastings disclosed that 'Although the invention has been described primarily in connection with special and preferred embodiments, it will be understood that it is capable of modification without departing from the scope of the invention (col.7)'. Thus, the combination of Hasting's composition with '642 or '776 would have been obvious to ordinary artisan considering each composition was intended as a health-food, each composition contained Ginseng, and further that the composition disclosed by Hastings could have been advantageously modified to include the composition which was disclosed by '642 or '776 to include additional nutritional/medicinal ingredients.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sha et al. (US 2001/0055624 A1) or Sha et al. (US 6,280,776 B1) in view of Castleman (1991) in view of Lust (1974) in view of Ericsson (US 5,773,241) in view of Hastings (US 5,567,424). as applied to claims 3, 4, 6, and 10 above, and further in view of Brown (1985).

The teachings of Sha et al. (US 2001/0055624 A1), Sha et al. (US 6,280,776 B1), Castleman (1991), Lust (1974), Ericsson (US 5,773,241) and Hastings (US 5,567,424) were discussed *supra.*

None of the references specifically disclosed wherein the composition contained 5-100 parts of wild ginseng, 100 parts by weight or less of the herb medicine, an 'ordinary' amount of vitamins and amino acids, or 200 parts or less of grains and vegetables.

Varying amounts of particular constituents within known, beneficial nutritional compositions was routine in the art of pharmacology. Brown (1985), discussing the protocol of the ancient herbalist commented:

"An herbalist had his own mixing bowls and measuring devices so that he would know exactly the amount of the medicine reaching the patient without overmedicating him. He also had to know the patient well so as to prescribe the particular plant mixture that would integrate into the patient's life-style, body condition, size and need." (P.32).

One of ordinary skill in the art would have been motivated to have varied the amounts of each of the individual constituents in the composition manufactured a nutritional supplement which would be equally beneficial to people of varying ages and weights. It was well known in the art, as evidenced by Brown, that medicinal herbal preparations were administered according to varying physical characteristics of the patient such as weight and condition of body because medicinal herbals, as well as medicines in general, effected individuals differently dependant upon these conditions. For example, a woman who was heavy may have needed more of a particular medicine/medicinal supplement to manifest a certain pharmaceutical effect, wherein a woman of lesser weight may have needed a smaller quantity of said medicine/medicinal supplement to produce an analogous effect.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220 The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

February 6, 2003

Patricia Patten